REMARKS

Claims 1, 3-4, 6-7, 9-10, 12-16, 18-24, and 26-27 are pending in the subject application. In the present Office Action, all pending claims stand rejected. In addition, claim 27 is objected to. In particular, claims 9-10, 12, 18-20, and 26 stand rejected under 35 U.S.C. 112, first paragraph for lacking enablement. Claims 1, 3, 6-7, 13-16, 21, 23-24, and 27 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by U.S. Patent No. 5,358,729 to Ohkuma et al. ("Ohkuma"). Claims 4 and 22 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Ohkuma. Applicant respectfully traverses the rejections of record as set forth herein.

Claim Objections

In the present Office Action, claim 27 stands rejected as being a duplicate of claim 24. The Examiner requests that Claim 27 be canceled. Applicant respectfully disagrees that claim 27 is a duplicate of claim 24. Specifically, claim 24 sets forth a method for producing a resistant starch, whereas, claim 27 sets forth a resistant starch formed from a process. In other words, claim 24 is a method claim and claim 27 is a product by process claim. The claims are therefore not duplicative. Applicant respectfully requests withdrawal of the objection.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 9-10, 12, 18-20, and 26 stand rejection under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner states that the specification does not provide enablement for making resistant starch with the claimed whiteness levels using the conditions claimed. Applicant traverses this rejection for the reasons set forth herein.

Applicant respectfully asserts that the claimed subject matter is fully enabled by the specification as originally filed. According to the MPEP, "[a]s long as the specification discloses at least one method of making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied." MPEP 2164.01(b) citing *In re*

Fisher, 427 F.2d 833, 839, 116 USPQ 18, 24 (CCPA 1970) (emphasis added). As the Examiner notes, the specification discloses three working examples where resistant starch having the whiteness levels of at least 65 is produced using the method claimed in the subject application. (Office Action, page 4, first paragraph). The specification also notes "while the examples use a whiteness level target of about 65 for the pyrodextrin, invention is not limited to this value." (Specification, paragraph [0040]). Those having ordinary skill in the art will recognize that the specification teaches a method wherein the selected pH is optimum to convert the unmodified starch to resistant starch having the claimed whiteness levels when at the reaction temperature. Further, one having ordinary skill would recognize that higher whiteness levels may be obtained using the claimed method and that whiteness levels of 65 were used for illustration purposes only.

Further, one skilled in the art would not have to carry out undue experimentation to practice the invention. As discussed above, Applicant has provided three working examples of practicing the claimed invention to produce of starch having a whiteness level of at least 65. In addition, Figure 1 clearly demonstrates that there is an optimum correlation between temperature and pH at which yield is maximized for a chosen whiteness level. "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." MPEP 2164.01. When considering whether undue experimentation was necessary to practice an invention, the Court in *In re Wands* held a specification as enabling when "there was considerable direction and guidance in the specification; there was a high level of skill in the art at the time the application was filed; and all of the methods needed to practice the invention were well known." MPEP 2164.01(a) citing *In re Wands* 858 F.2d 731, 740, 8 USPQ2d 1400, 1406 (Fed. Cir. 1988) (internal quotations omitted). In the present application, the specification provides considerable direction for practicing the claimed invention (including three working examples), the level of skill of one in the art is high (as the Examiner notes, the level of skill would be of one having experience in organic synthesis (Office Action, page 3)), and the chemical procedures needed to practice the invention are well known. Therefore, given the disclosure in the

specification, one having ordinary skill in organic synthesis would not have to perform undue experimentation to practice the invention.

Finally, the Examiner states that based on the disclosure of the Ohkuma reference, the same level of whiteness cannot be obtained by heating the acidified starch to three different temperatures. (Office Action, page 4). Applicant respectfully disagrees with this statement and draws the Examiner's attention to Figure 1 and Examples 1-3 of the subject application where the same levels of whiteness (i.e., at least 65) was obtained by heating acidified starch to temperatures of 140°C, 150°C and 170°C. The fact that Ohkuma does not disclose the invention only serves to demonstrate that the claimed method is novel and non-obvious over the Ohkuma reference. Further, while the Examiner cites Ohkuma to demonstrate non-predictability in the art, Applicant notes that "even in unpredictable arts, a disclosure of every operable species is not required." MPEP 2164.03. Applicant asserts that the specification, including three working examples demonstrating the claimed invention, fully enables one having ordinary skill in the art to practice the invention. Withdrawal of the rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claims 1, 3, 6-7, 13-16, 21, 23-24, and 27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ohkuma. Applicant traverses this rejection for the following reason.

For a reference to be anticipatory under 35 U.S.C. § 102, it is axiomatic that the reference must teach, either explicitly or inherently, each and every element of the invention as set forth by the claims. As set forth herein, Ohkuma does not teach or suggest each an every element of the claimed invention.

Claim 1 of the subject application sets forth a method of producing resistant starch comprising: selecting a reaction temperature of about 140°C to about 180°C; acidifying unmodified starch to a selected pH of about 1 to about 4 with hydrochloric acid, wherein said selected pH is optimum to convert said unmodified starch to resistant starch when at said reaction temperature; heating said acidified unmodified starch to said reaction temperature; and maintaining said acidified

unmodified starch close to said reaction temperature until a maximized yield of resistant starch has been obtained while maintaining a whiteness level between about 60 and about 100.

As the Examiner notes, Ohkuma teaches a treatment of corn starch at temperatures of 130°C to 170°C (column 14, lines 30-52). However, as the Examiner also highlights, the maximum whiteness level of the product obtained by Ohkuma within the temperature range set forth in claim 1 of the subject application (i.e., about 140°C to about 180°C) is only 50.5. (See, Ohkuma, column 23, Table 13). Ohkuma does not disclose heating the acidified unmodified starch to the reaction temperature (of about 140°C to about 180°C and maintaining the acidified unmodified starch close to said reaction temperature until a maximized yield of resistant starch has been obtained while maintaining a whiteness level between about 60 and about 100. At these temperature ranges, the Ohkuma process produces whiteness levels of 50.5 or less. Thus, Ohkuma does not teach or suggest every element of the claims of the subject application.

Further, in the Office Action the Examiner states that Ohkuma teaches an inverse relationship between whiteness and temperature (see Ohkuma column 23, Table 13) and that "based on the results disclosed by Ohkuma one of ordinary skill in the art would not conclude that heating acidified starch to different temperatures as instantly claimed will produce a whiteness level of 65." (Office Action, page 4). Indeed, the Examiner recognizes that the claimed process is novel and non-obvious over the Ohkuma process. Applicant respectfully requests that the rejection of claims 1, 3, 6-7, 13-16, 21, 23-24, and 27 under 35 U.S.C. § 102(b) be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 4 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ohkuma. Applicant traverses the rejection as set forth herein.

To establish a case for *prima facie* obviousness, three basic criteria must be met: a) there must be some suggestion or motivation to modify the reference or to combine the reference teachings; b) there must be a reasonable expectation of success; and c) the prior art reference(s) must teach or suggest all the claim limitations. MPEP 2143. Applicant submits that *prima facie* obviousness has not been established

for at least the reasons that the prior art reference(s) do not teach or suggest all the claim limitations and there is no suggestion or motivation to modify the reference. Further, it is submitted by Applicant that the cited reference teaches away from the claims of the subject application.

Claim 4 and claim 22 depend from claim 1 of the subject application. As discussed above, Ohkuma does not teach or suggest heating the acidified unmodified starch to the reaction temperature (of about 140°C to about 180°C) and maintaining the acidified unmodified starch close to said reaction temperature until a maximized yield of resistant starch has been obtained while maintaining a whiteness level between about 60 and about 100 as recited by claim 1. Ohkuma teaches a maximum whiteness level of 50.5 within the reaction temperature range of 140°C to 180°C. Therefore Ohkuma does not teach or suggest each and every element of claim 4 or 22. In fact, Ohkuma teaches away from a whiteness level between about 60 and about 100 at these reaction temperatures. Ohkuma discloses a whiteness level of 50.5 at a temperature of 140°C and states that there is an inverse relationship between temperature and whiteness level (i.e., higher temperature results in lower whiteness levels). Thus, Ohkuma teaches that reaction temperatures higher than 140°C would result in starch having a whiteness of less than 50.5. Given this teaching by Ohkuma, it would not be obvious to one having ordinary skill in the art that the claimed whiteness levels could be achieved at the claimed reaction temperatures.

Further, there is no teaching or motivation in Ohkuma that gaseous hydrochloric acid could be used in place of aqueous hydrochloric acid. Ohkuma only discloses hydrochloric acid in the form of an aqueous solution having a concentration of about 1%. (Ohkuma, column 6, lines 41-45). The fact that a reference can be combined or modified is not sufficient to establish *prima facie* obviousness and the fact that modification of the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish *prima facie* obviousness. See MPEP 2143.01. There "must be a suggestion or motivation in the reference [to make the modification]." *In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990). There is no such suggestion in Ohkuma.

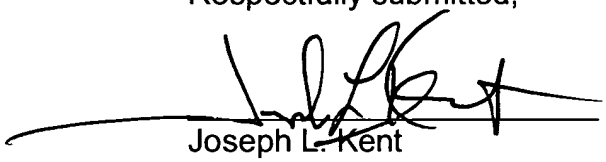
Prima facie obviousness has not been established by Ohkuma. First, Ohkuma does not teach or suggest each and every element of the claimed invention. Second, Ohkuma specifically teaches away from the use to the claimed temperatures to give the claimed whiteness levels. Finally, Ohkuma does not teach or suggest use of gaseous hydrochloric acid. Moreover, Ohkuma fails to disclose the selection of pH that is optimum to convert the unmodified starch to resistant starch when at the reaction temperature to afford a maximized yield of resistant starch while maintaining the claimed whiteness levels. Applicant respectfully requests that the rejection of claims 4 and 22 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

Applicants submit that claims 1, 3-4, 6-7, 9-10, 12-16, 18-24, and 26-27 of the subject application recite novel and non-obvious methods for producing a resistant starch. In view of the remarks presented above, Applicants respectfully submit that the subject application is in condition for allowance. Accordingly, reconsideration of the rejections and allowance of all pending claims is earnestly solicited.

If the undersigned can be of assistance to the Examiner in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below.

Respectfully submitted,



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